

EXHIBIT 35

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EXPERT REPORT OF JANE C. BALLANTYNE, M.D., F.R.C.A.

MARCH 25, 2019

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I. INTRODUCTION

1. My name is Jane C. Ballantyne, M.D., F.R.C.A. I have been retained by Plaintiffs Cuyahoga County and Summit County to offer my expert opinions on issues related to the medical use of opioids for the treatment of pain, the conduct of opioids manufacturers relating to the marketing and promotion of prescription opioids, the influence of these companies on the standard of medical care for the use of prescription opioids in the United States, the evidence relied on by the manufacturers in support of the use of chronic or long-term use of opioids, and the indications for opioid use, and related topics.

2. My curriculum vitae, a copy of which is attached as **Exhibit A**, describes my education, background, qualifications, and my publications. I have not testified in deposition or at trial in the last four years.

3. I am being compensated at a rate of \$600 per hour for my services in this litigation. I am also being reimbursed for all reasonable expenses incurred for my work on this litigation. No part of my compensation is contingent upon the outcome of this litigation, and I have no interest in the litigation or with either party.

4. This report contains a true and accurate statement of my opinions in this matter. The matters cited in this expert report are based on my personal knowledge, education, and years of medical experience and, if called to testify, I will testify to the same effect. These opinions are based on my education, training and experience as well as the data, evidence, and literature cited herein and are offered to a reasonable degree of medical certainty. I reserve the right to supplement my analysis and opinions based on additional evidence or information that is made available to me after the date of this report, including additional expert disclosures made after March 25, 2019 as approved by the Court.

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4. Changes in the mid-1990s: the introduction of OxyContin

In the mid-1990s, at the same time as market forces propelled chronic pain management to primary care practice, the teaching on chronic pain took on a very different tone. This was a change in tone that began in the pain field, but spread rapidly beyond the field itself as a result of the aggressive marketing of OxyContin and other patented opioid formulations. Certain clinicians, most prominently Foley and Portenoy as discussed above, having successfully used opioids to address patients' pain at the end of life (usually cancer-related), argued that the pain suffered by chronic pain patients was equal to that suffered by cancer patients, and therefore chronic pain should not be treated any differently.[13] [1] The new teaching emphasized that change was needed: we should not have allowed the stigma of addiction to interfere with pain relief. This message was strongly endorsed by Purdue and other pharmaceutical companies that manufactured opioids, and the drug company representatives who frequented MGH and the pain clinic in the 1990s reiterated this message. Without this endorsement and amplification, it is unlikely, in my opinion, that this message would have spread beyond the realm of academic pain specialists. The pharmaceutical companies provided financial support for medical education, and created speakers' bureaus made up of "thought leaders" and other physicians who advocated use of opioids for chronic pain. Wittingly or not, leading "pain specialists," mostly from the cancer and palliative care fields, became well-known and effective proselytizers for the expanded use of opioids for the treatment of chronic pain. I also became aware, through reading medical journals and the press and attending meetings, of the efforts of industry to influence medical prescribing guidelines, to encourage use of opioids and discourage state-level restrictions on their use, namely through industry's presence at medical meetings, the availability of branded teaching materials, and industry's distribution of favorable papers.[20-23]

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other opioid manufacturers were able to significantly influence physicians' willingness to prescribe opioids long-term for pain.

2. Sponsoring professional bodies and guidelines

As has been well documented, opioid manufacturers provided financial support to U.S. pain societies, including the American Pain Society and the American Academy of Pain Medicine.[36] The messaging of these pain societies was consistently in favor of expanding opioid use. In 1997, for example, the American Pain Society and the American Academy of Pain Medicine published a "consensus statement" on opioid use for treatment of chronic pain, stating that studies showed that when opioids are taken for pain, the risk of addiction is low.[23] One of the co-authors of the consensus statement, Dr. David Haddox, was at that time a paid consultant for Purdue Pharma, and later became an employee and eventually an executive of the company. To me and many other physicians at that time, the publication of something called a "consensus statement" by two respected professional bodies represented the accepted thinking and best standards for treating pain.

Opioid manufacturers were also a very obvious presence at pain meetings in the late 1990s and early 2000s. I was a member of the American Pain Society as it was the American chapter of the IASP. The opioid manufacturers would sponsor special lunches at our national meetings, and these free lunches were always well attended. I believe they had a lot of influence. We were all part of the initial enthusiasm for opioids at these meetings, because we thought that expanding opioid use to chronic pain patients was a way we could help people. Having been taught that the risk of addiction was low and that there was no reason to withhold opioids from people suffering from chronic pain, we believed we could make people's lives better using these drugs. By the mid-2000s, however, many of us had become aware of the influence of manufacturers in our own professional organizations. Some of my colleagues stopped their

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membership for this reason. I spoke out about the problems with chronic opioid treatment at the American Pain Society annual meeting in 2005 and was vilified for doing so. Although I have emphasized pharma's role in underwriting pain groups and pain meetings, pharma did actually reach more widely to other professional bodies, especially in sponsoring their pain guidelines which exaggerated the benefits of opioids, deceptively downplayed their harms, and exaggerated the harms of alternatives to opioids such as over-the-counter pain relievers.[22, 37]

3. Sponsoring of patient advocacy groups

In this respect, pharma has taken distressed and vulnerable people and used them to claim often exaggerated and ill-informed benefit for their opioid therapy. Many patients who are already established on opioid therapy believe very strongly that the treatment is helping them and are anxious about the prospect of being deprived of opioids. The public speakers and writers among them make compelling advocates for their treatment, notwithstanding the ample evidence showing that long-term opioid use for, in particular, chronic pain is usually not recommended. The industry has in my view taken advantage of this situation. There is even evidence that opioid manufacturers have provided funding for what are presented as grassroots patient advocacy groups that have resisted efforts to decrease opioid prescribing. For example, the American Pain Foundation's 2010 Annual Report, which was made publicly available as part of an investigative report, reported 88% of its annual income as "Industry Income"—over half from one of the major opioid manufacturers, Endo, and an Endo-sponsored organization, the National Initiative on Pain Control (NIPC).[38]

4. Medical education

The many ways in which pharma can influence medical practice are well known.[39, 40] These include providing high production quality educational materials for prescribers and patients, funding of continuing medical education, presence in hospitals and doctors' offices,